DAIDS Guidelines for Good Clinical Laboratory Practice Standards
Frequently Asked Questions

This document provides answers to the frequently asked questions (FAQs) regarding the DAIDS Guidelines for Good Clinical Laboratory Practice Standards deployment.

General

Are these guidelines or standards?
The sections within the document list standards for DAIDS funded laboratories. There are no US regulatory standards or guidelines for GCLP. The appendices supply general guidance that may be helpful in developing policies, procedures or forms that will assist in meeting the standards.

Are research assays that are completed in regional or local labs falling under these standards?
The document applies to all laboratories performing testing that supports a clinical trial funded and/or sponsored by the Division of AIDS.

Are these standards for vaccine studies or for all DAIDS funded studies?
The document applies to all laboratories performing testing that supports a clinical trial funded and/or sponsored by the Division of AIDS.

When the standards say documentation should be "readily available", what does this mean?
Generally, the industry standard considers "readily available" to be within 24 hours.

What if a Laboratory Director deems these standards as unattainable?
If the Laboratory Director of a DAIDS funded facility determines that any of the standards cannot be met, the laboratory Director should notify DAIDS and provide an explanation for why the standards are unattainable.

Are the appendices of the standards to be used exactly as they are for compliance with associated standards?
The appendices are provided in an effort to assist the reader in developing customized policies, procedures or forms, and are not intended to be used exactly as they are provided in the document.

Do study plans and analytical plans pertain to processing labs?
This is an option if the study protocol is considered inadequate. Often, study protocols may not address all tasks and processes that must be carried out by laboratory personnel when working with clinical trial specimens; in this case, a formal laboratory-specific supplement in the form of an analytical or study plan should be developed.

Are study/analytical plans required for all protocols?
Study/Analytical Plans are optional for laboratory staffs who consider a study protocol inadequate in the description of laboratory-specific tasks and processes required for the trial.

Testing Facilities and Operations

Where should master SOPs be stored?
The laboratory management should decide where to store master SOPs.

What defines attachments in a standard SOP format?
The laboratory management/staff should determine what should be an attachment to an SOP. Product inserts and a preventative maintenance schedule from an instrument manual are both examples of what could be an attachment.

External Quality Assurance

The standards state that the DAIDS requires all laboratories receiving funding to be enrolled in EQA programs for all testing used to support clinical trial research. Does this include back-up or contract labs who may receive funding directly from the DAIDS?
Any laboratory receiving funding from the DAIDS should have all applicable assay systems enrolled in an EQA program. DAIDS is dependent on every single laboratory, whether primary, contract or back-up, to generate quality and accurate data in support of product licensure.

The standards state that laboratories should enroll in EQA programs for all testing used to support clinical trial research and that cover all study protocol analytes. Does this apply even if the study is not for the purpose of product licensure?
Yes, EQA is required for all DAIDS funded laboratories, because laboratory-generated datasets may be used for purposes that were unplanned at time of data accrual.

Organization and Personnel

The standards state that the DAIDS will audit all laboratories that are involved with its clinical trials on an annual basis (or as deemed necessary) to confirm GCLP compliance. Is the DAIDS going to include CLIA/CAP labs in the US?
DAIDS does not currently audit US labs that are CLIA certified.

Will DAIDS continue to audit non-CLIA/CAP where other accreditation such as ISO7025/15189 or national accreditation exists?
Yes, DAIDS will continue to audit labs that are not certified by CLIA. For those international labs that have CAP or SANAS accreditation, DAIDS will audit those labs during the year that the lab is NOT inspected by CAP. DAIDS can, however, audit any DAIDS funded laboratory for cause at any time if needed.

To whom should organizational charts be available? Do they need to be on display?
The charts should be available to the individuals working in the laboratory, or who have been cleared to enter the laboratory.

Does documentation relevant to performance evaluations for staff in the laboratory need to be available to the monitors?
No, portions of personnel files such as performance evaluations or health records can be withheld if the management determines they are inappropriate for review.

Does staff identification have to be on display?
No, but the link/signature sheet should be available for review in order to associate codes, initials, signatures, or other markings used in identifying staff to a full printed name.

Who is permitted to have access to documentation of equipment maintenance in the laboratory?
Documentation of equipment maintenance is accessible to the laboratory staff and those granted access to the laboratory.

Equipment

Does the DAIDS have any acceptability criteria for adjustable and fixed-volume automatic pipettors?
No, the laboratory staff should determine their own acceptability criteria. The laboratory management is responsible for utilizing any manufacturer material and statistical tools to establish such criteria.

Is there a list of certified alternatives to NIST?
Some countries have their own standards organizations. The list would be country-specific.

Are there any recommendations for any acceptability criteria for thermometers?
It is the laboratory management's responsibility to utilize manufacturer's data and statistical tools to determine their acceptability criteria. For safety reasons, the use of mercury thermometers is discouraged.

What should a laboratory do in the event there is no way to check the temperature of the thermocyclers in modern real time PCR systems, using an external NIST certified device?
In this special case, the laboratory would just need to document the situation and their plan to maintain the equipment.

Do humidity and CO2 levels need daily monitoring and documenting in the laboratory?
The DAIDS GCLP Standards state that humidity and CO2 should be monitored as required by the manufacturer.

Not all centrifuges have the ability for measuring speed and temperature. Any guidance in this situation?
These standards target commonly used equipment. Any unique situations should be handled as required by the manufacturer and documented.

If NIST is unavailable for timers, what alternatives are acceptable (i.e. computer clock, mobile phone clock)?
All alternate approaches for timer calibration/checks should be documented.

Does the manufacturer always perform certification of biosafety cabinets/laminar air flow hoods?
The DAIDS GCLP Standards states that certification can be provided by a trained service technician, certified maintenance department or company.

If humidity is a requirement, then would all laboratories be required to add instrumentation to monitor and document temperature and humidity controls?
This is required if the manufacturer has set humidity ranges for any equipment, reagents or assay.

Records and Reports

How is "ready identification" defined?
"Ready identification" indicates that there should be no interpretation needed to identify the origin of a subject in specific test reports and records.

How is "fire proof" storage defined?
Records should be stored in a manner in which they are protected from fire; or, duplicated such that if a fire occurs in a storage area, the data could be accessed via the back-up method.

Specimen Transport

Is there a guideline to define at what point sample transportation becomes sample shipping? When do IATA rules need to be followed, and when do DOT or other country rules need to be followed?
The DAIDS GCLP Standards make no distinction between transport and shipping. The document does state that all federal and local regulations should be followed.

To ensure that specimens are shipped within the temperature interval specified, does the actual measured temperature of each shipment need to be noted and documented?
Yes, the temperature should be noted and documented if a temperature requirement is present for the specimen.

The standards state that shipments must be prepared by following all federal and local transportation of dangerous goods regulations (i.e. IATA). Does this refer to the transportation from clinic to lab?
If that transport from clinic to lab requires air, rail or road travel, the applicable federal and local regulations must be followed.

The standards state that laboratory personnel who ship specimens must renew regulation training every two years. To which regulation do the standards refer and what training needs to be completed?
This statement refers to IATA regulation. IATA training should be completed every two years. Re-training should occur if there are changes in the regulations during the interim.

Does sample storage require 24-hour monitoring, or is daily recording sufficient?
Both 24-hour monitoring and daily temperature recording are needed. Monitoring can be accomplished in several ways; computerized system, 24-hour staffing (security guard), etc.

Is there an issue of too much information in the identifiers? Some reference lab computer systems require DOB, gender or initials, even if they are not required for correct reference ranges. Are initials of DOB/gender confidentiality issues if they are not needed for reference ranges?
Individual labs will have to determine what identifiers they will be using, and if those identifiers compromise confidentiality.

How many identifiers are required on a specimen container label?
There should be at least one unique subject identifier. Networks also have their own requirements and should be consulted.

Safety

Fire blankets are not mentioned in the list of safety equipment for personnel safety; however, they are listed on the audit checklist. Any guidance?
Fire blankets are not required, but were listed among other items as examples of safety equipment on an earlier audit checklist. Since this seems to be a point of confusion, the example of fire blankets has been removed from the audit shell.

A laboratory may also be a clinic room where clinical testing is performed. The requirements for safety equipment should be applicable to the use and location of the laboratory. In this case, who would be responsible for enforcing this requirement in the clinic?
These standards are for laboratories. Unless the clinic is a point of care laboratory (POC), these standards do not apply. If the clinic is a POC, the internal staff would have to determine responsibility.

In regards to Personal Protective Equipment (PPE), what are acceptable gowns and lab coats?
This level of detail should be determined by the laboratory staff.

What if Material Safety Data Sheets (MSDS) are not provided by the manufacturer?
There are many resources that are free of charge on the internet, such as MSDS.com.

What if MSDS are not available in the local language of the location of the laboratory?
This is unlikely; however, should this occur, a DAIDS representative should be contacted.

Who is responsible for ensuring that phlebotomy and clinic staff, as well as drivers, have received safety training? Does the lab need to keep those records?
The laboratory leadership is responsible, along with the individuals themselves, for receiving training and keeping it updated. These records should be accessible. Maintenance of these records is determined by the onsite leadership.

Laboratory Information Systems

Computer time-stamped audit trails must be used by the LIS. Is the LDMS compliant?
If the LDMS accommodates time-stamped audit trails, then it would be compliant with this particular standard.

Quality Management

Are internal audits/self-assessment results available to external auditors (i.e. PPD or FDA)?
Internal audit reports may be withheld from the FDA.

The laboratory must have a list of assay turnaround times readily available. Would this list include processing times (i.e. PBMCs, serum/plasma storage)?
Processing time is a large part of the pre-analytical process and should always be included in the assay turnaround time.